

App. No. 10/520,330
Office Action Dated January 16, 2007

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REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. Claims 1 and 9 have been amended. The limitation in claims 1 and 9 concerning a higher osmotic pressure and a lower osmotic pressure is supported by for example page 5, line 35 to page 6, line 7. The limitation in claims 1 and 9 concerning assessing both an amount of peritoneal dialysis fluid and a concentration of monitored solutes for each time of the fluid drain is supported by for example page 5, lines 7 to 17 and Figure 2. The limitation in claims 1 and 9 concerning performing a PET by infusing a dialysis fluid is supported by for example Figure 2. The limitation in claims 1 and 9 concerning performing a blood test in order to assess concentrations of the monitored solutes is supported by for example page 6, lines 21 to 26. The limitation in claims 1 and 9 concerning the repetition of the fluid infusion and the fluid drain is supported by for example page 8, line 19 to page 9, line 9. Claims 12 and 13 have been canceled without prejudice or disclaimer. Claims 1, 3-4 and 9-11 are pending. No new issues are raised by the revisions, and therefore this Amendment should be entered.

Claim rejections – 35 U.S.C. §112

Claims 1, 3, 4 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to claim the subject matter of the present invention. Claims 1 and 9 have been amended, taking the issues noted in the rejection into account. Applicants submit that claims 1 and 9, and the dependent claims therefrom are definite.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

App. No. 10/520,330
Office Action Dated January 16, 2007

Claim rejections - 35 U.S.C. § 103

Claims 1, 3, 4, and 7-9 have been rejected under 35 U.S.C. 103(a) as obvious over Chen et al. (U.S. Patent No. 5,670,057) in view of Milner (U.S. Patent No. 6,077,836) and Kelton et al. (1978). Applicants respectfully traverse this rejection.

Claims 1 and 9 require the repetition of the fluid infusion and the fluid drain to be performed in the order such that the dialysis fluid of the higher osmotic pressure is used for the first and the last times. If the dialysis fluid having the higher osmotic pressure is infused first, a long dwell time can be secured, thereby permitting apt conditions for starting the repeated fluid infusion in the evening (see page 9, lines 10-14). On the other hand, if the dialysis fluid having the lower osmotic pressure is infused, a shorter dwell time is obtained, such that fluid infusion and drain must be carried out at short intervals, thereby affecting the lifestyle of the patient (*Id.*). The claims also require the dialysis fluid used for each of the times other than the first and last fluid infusion and drain steps to be determined so that the dialysis fluid of the higher osmotic pressure is not continuously used. If the dialysis fluid of the higher osmotic pressure is not used continuously, it is possible to prevent excessive water removal (see page 8, lines 19-22). The claims further require setting the dwell time from when the dialysis is infused until when the dialysis is drained to be different each time when using a dialysis fluid having the same osmotic pressure. These features allow curve fitting of a curved line, which expresses the change over time in the water removal amount and the change over time in the solute concentration, to be performed precisely (page 5, lines 7-10).

More specifically, the curved line is obtained by curve fitting based on at least three types of clinical data for different dwell times when using a dialysis fluid having the same

App. No. 10/520,330
Office Action Dated January 16, 2007

osmotic pressure. These test sampling points are set in the time interval where there is the greatest change in the amount of water removal, that is, sampling points where there is the greatest amount of change in the curved line (page 5, lines 10-15). In this way, higher precision curve fitting is achieved, and as a result, a peritoneal dialysis simulation becomes possible (page 5, lines 15-17).

The advantageous effects of the claims are demonstrated in the experimental work of the present specification. Briefly, dialysis fluids having high and low osmotic pressure were infused in alteration (page 8, lines 19-21). Then, three types of clinical data for different dwell times were collected as required by claims 1 and 9 (Id.). As indicated in Figs. 6 and 7, by appropriately performing curve fitting based on dwell times of three different lengths for dialysis fluids having the same osmotic pressure, the curved lines expressing the change over time in the water removal amount and the change over time in the solute concentration of the drain fluid were obtained.

The rejection relies on Milner for a method for performing a peritoneal dialysis. The rejection's reliance is misplaced. Although Milner teaches the repeated infusion and drain of two dialysis fluids having different osmotic pressures, nonetheless, Milner teaches a dwell time from when the dialysis fluid is infused until when the dialysis fluid is drained to be set with the same dwell times when using dialysis fluid having the same osmotic pressure, i.e., three exchanges of two litre 1.36 wt. % glucose with 4 hr. dwell times (col. 30, lines 20-25). On the other hand, claims 1 and 9 require the step of performing fluid infusion and fluid drain a plurality of times using dialysis fluids with the same osmotic pressure with the dwell times being different each time. Moreover, Milner teaches using a

App. No. 10/520,330
Office Action Dated January 16, 2007

dialysis fluid of the lower osmotic pressure for the first of the fluid exchange steps, thereby teaching away from claims 1 and 9.

The rejection contends that Milner clearly discloses a method wherein the fluid drain and fluid infusion is performed at least three times for each of two dialysis fluid with different osmotic pressures (1.36% glucose and 5% glucose polymers) wherein the dwell times are different each time when using a dialysis fluid having the same osmotic pressure (6hrs, 8hrs and 12 hrs), and presumably refers to column 29, lines 1-30 of Milner.

However, in the Phase 3 study disclosed in Milner, patients were first subjected to three consecutive two litre exchanges with 5% glucose polymer 2 solutions. Then in another separate study, the patients were subjected to three consecutive two litre exchanges with 1.36% glucose solution. On the other hand, claims 1 and 9 require repeated fluid exchanges to be performed in one continuous procedure, alternating between dialysis fluids having a higher osmotic pressure and a lower osmotic pressure. Therefore, claims 1 and 9 are distinguishable over Milner.

Kelton teaches the performance of a blood test last of all steps. However, Kelton likewise fails to teach or suggest using three different dwell times for dialysis fluids having the same osmotic pressure. Accordingly, even if Chen, Milner and Kelton are combined, the references would still fail to meet claims 1 and 9.

In consideration of the forgoing, it is clear that Chen, Milner and Kelton fail to teach or suggest the features required by claims 1 and 9. Therefore, claims 1 and 9 and the dependent claims therefrom are patentable over the references, taken together or separately.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

App. No. 10/520,330
Office Action Dated January 16, 2007

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

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